SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-009

Tesio® Catheter Sets

IMPORTANT INFORMATION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

This SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

Applicable Documents	
Document Type	Document Title / Number
DHF	05013, 05014, 05040, 06009, 96006
'MDR Documentation' File Number	MDR-009

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**05OCT2021**	**26536**	**RS**	**Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
2	**11JUL2022**	**27030**	**RS**	**Scheduled Update; updated SSCP in accordance with CER-009_C. In addition, the following elements were added throughout: Basic UDI-DI, SRN, Notified Body name and single identification number, EMDN nomenclature, quantification of residual risks, benefits and risks related to alternative therapies, required training for home hemodialysis, and acronym table.**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	**12SEP2022**	**27280**	**GM**	**Added additional information to Revision 2 row. The total case numbers identified and used for clinical performance evaluation displayed in Section 5 has been updated from 2,939 to 3,080 as a result of corrections to the case numbers sourced from several articles and the removal of Wivell et al., 2001. After these corrections, 3,003 cases from 29 literature articles represent the clinical evidence sourced from published literature.**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
4	**07JUL2023**	**28266**	**GM**	**Periodic Update; Updated in**	☐ Yes, this version was

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
				Accordance with CER-009, Revision D	validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
5	**01JUL2024**	**29458**	**GM**	**Periodic Update; Updated in Accordance with CER-009, Revision E**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
6	**05SEP2025**	**25-0169**	**GM**	**Periodic Update; Updated in Accordance with CER-009, Revision F**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					by the Notified Body as this is a Class IIa or IIb implantable device

USERS / HEALTHCARE PROFESSIONALS

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1. Device identification and general information

Device trade name(s)	Tesio®, Duo-Jet® II , Chronic Twinline
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Manufacturer single registration number (SRN)	US-MF-000008230
Basic UDI-DI	00884908278NQ
Medical device nomenclature description / text	F900202 – Permanent Hemodialysis Catheter and Kits
Class of device	III
Date first CE certificate was issued for this device	January 1996
Authorized representative name and SRN	European Regulatory Expert Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany SRN: DE-AR-000005009
Notified Body name and single identification number	BSI Netherlands NB2797

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays, in various configurations inclusive of accessories and adjunctive devices (see section “Accessories intended for use in combination with the Device”).

Variant Devices:

Variant Description	Part Number	Explanation of Multiple Part Numbers
10F x 52cm Tesio (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)	10196-818-600-1 10196-821-100-1 10196-818-600S 10196-821-100S 10196-821-100-1	No significant clinical, biological, or technical difference (only difference is with or without pre-loaded stylet, or if only a single catheter is included)
10F x 52cm Tesio (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)	10196-822-600-1 10196-825-100-1 10196-822-600S 10196-825-100S	No significant clinical, biological, or technical difference (only difference is with or without pre-loaded stylet, or if only a single catheter is included)

Variant Description	Part Number	Explanation of Multiple Part Numbers
	10196-825-100-1	
10F x 52cm Tesio (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)	10196-827-600-1 10196-830-100-1 10196-827-600S 10196-830-100S 10196-830-100-1	No significant clinical, biological, or technical difference (only difference is with or without pre-loaded stylet, or if only a single catheter is included)
10F x 70cm Tesio (Arterial Cuff - 46cm From Tip) (Venous Cuff - 50cm From Tip)	1566S 1567S	N/A

Procedure Trays:

Catalog Code	Part Number(s)	Description
BFL-6E.	10196-827-600-1 10196-830-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFR-6E.	10196-822-600-1 10196-825-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFS-6E.	10196-818-600-1 10196-821-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
BFL-6SE.	10196-827-600S 10196-830-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFR-6SE.	10196-822-600S 10196-825-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFS-6SE.	10196-818-600S 10196-821-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
BFLS	10196-830-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 30cm From Tip)
BFRS	10196-825-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 25cm From Tip)
BFSS	10196-821-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 21.2cm From Tip)
BFR1070KDS	1566S 1567S	10F x 70cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 46cm From Tip) (Venous Cuff - 50cm From Tip)
NITSL21K	10196-818-600-1 10196-821-100-1	10F x 52cm Chronic Twinline Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
NITSL25K	10196-822-600-1 10196-825-100-1	10F x 52cm Chronic Twinline Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
DJLT2000L	10196-827-600-1 10196-830-100-1	10F x 52cm Duo-Jet® II Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
DJLT2000R	10196-822-600-1 10196-825-100-1	10F x 52cm Duo-Jet® II Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)

Configurations of Procedure Trays:

Configuration Type	Kit Components
Dual Tesio® Catheter Set	(2) Catheter (2) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (2) 0.97mm x 70cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (4) Tunneler (1) 2.1mm ID x 15cm (6F) Dilator (2) 3.4mm ID x 17cm (10F) Valved Peelable Introducer (1) Arterial Extension Set (1) Venous Extension Set (2) Clamp (2) Catheter Plug (2) End Cap (1) Catheter Securement Device (1) Patient ID Card (1) Patient Information Packet
Dual Tesio® Catheter Set w/ Stylet	(2) Catheter (2) Stylet: (52CM Kits) 1.9mm OD 1.1mm ID x 541mm (.042 X .075 x 21.28) Stylet (70CM Kits) 1.9mm OD 1.1mm ID x 741mm (.042 X .075 x 29.16) Stylet (2) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (2) 0.97mm x 100cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (4) Tunneler (1) 2.1mm ID x 15cm (6F) Dilator (2) Valved Peelable Introducer: (52CM Kits) 3.4mm ID x 17cm (10F) Valved Peelable Introducer (70CM Kits) 3.7mm ID x 18cm (11F) Peelable Introducer (1) Arterial Extension Set (1) Venous Extension Set (2) Clamp (2) Catheter Plug (2) End Cap (1) Catheter Securement Device (1) Patient ID Card (1) Patient Information Packet
Single Tesio® Catheter Set	(1) Catheter (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (1) 0.97mm x 70cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (2) Tunneler (2) 3.7mm ID x 18cm (11F) Peelable Introducer (1) Venous Extension Set (1) Clamp (1) Catheter Plug (1) End Cap (1) Patient ID Card (1) Patient Information Packet

Configuration Type	Kit Components
Duo-Jet® II Catheter Set	(2) Catheter (2) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (2) 0.97mm x 70cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (4) Tunneler (1) 2.1mm ID x 15cm (6F) Dilator (2) 3.7mm ID x 18cm (11F) Peelable Introducer (1) Arterial Extension Set (1) Venous Extension Set (2) Clamp (2) Catheter Plug (2) End Cap (1) Catheter Securement Device (1) Patient ID Card (1) Patient Information Packet
Chronic Twinline Catheter Set	(2) Catheter (2) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (2) 0.97mm x 70cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (4) Tunneler (1) 2.1mm ID x 15cm (6F) Dilator (2) 3.7mm ID x 18cm (11F) Peelable Introducer (1) Arterial Extension Set (1) Venous Extension Set (2) Clamp (2) Catheter Plug (2) End Cap (1) Catheter Securement Device (1) Patient ID Card (1) Patient Information Packet

2. Intended use of the device

Intended purpose	Tesio® Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for single use only.
Indication(s)	Tesio® Catheters are indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis.
Target population(s)	Tesio® Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.

Contraindications and/or limitations	• Known or suspected allergies to any of the components of the catheter or the kit. • This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.

3. Device description

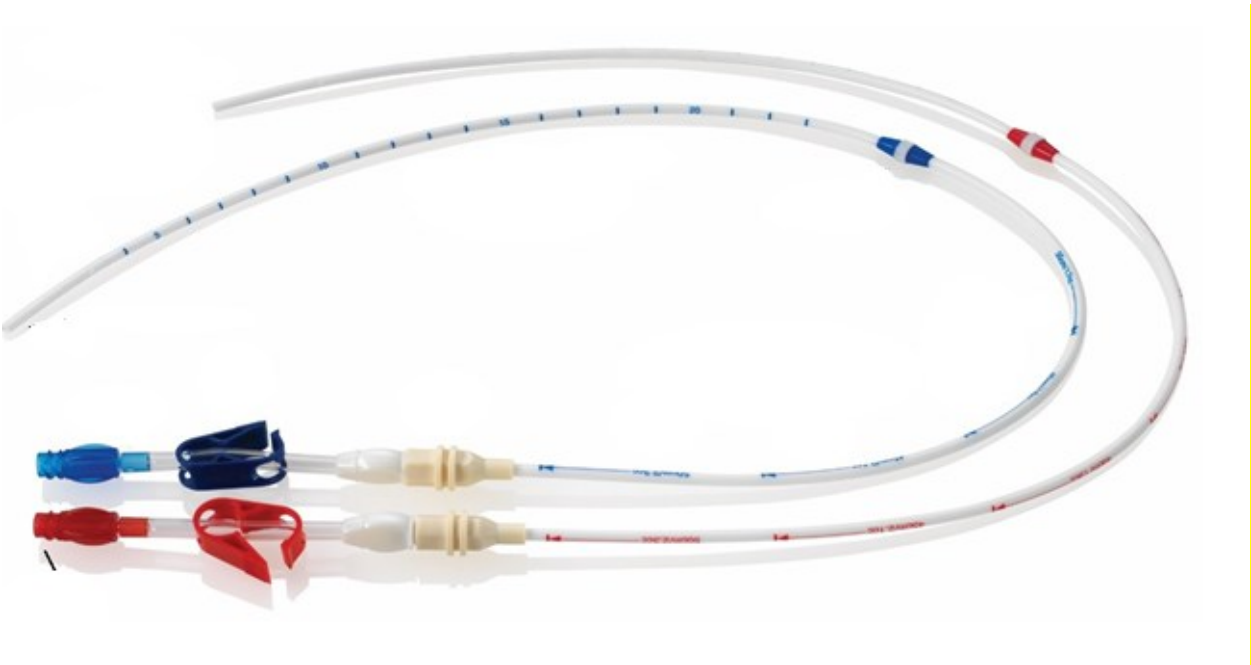

Figure 1: Tesio® Catheters

Description of device	The Tesio®/Duo-Jet® II/Chronic Twinline Catheter is a long-term single lumen catheter. Two catheters are inserted into the target vein that are used to remove and return blood through two separate passages (lumens). Priming volumes are printed on the lumen. A polyester cuff is placed on the catheter's lumen for tissue ingrowth to anchor the catheter. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray. The catheter has been tested at flow rates of up to 500 mL/min. The catheter is available in a variety of sizes and cuff locations to accommodate physician preference and clinical needs.
Materials / substances in contact with patient tissue	The percentage ranges in the table below are based on the weights of the 52cm catheters (18.02g) and the 70cm catheters (21.92g).

Material	**% Weight (w/w)**
Polyurethane	49.52 - 52.01
Acetal copolymer	22.35 - 24.37
Polyvinyl chloride	8.75 - 9.55
Nylon	4.35 - 4.74

<table>
<tr><td></td><td>
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<tr><td>Barium sulfate</td><td>8.19 - 8.64</td></tr>
<tr><td>Stainless Steel</td><td>1.97 - 2.14</td></tr>
<tr><td>Polyethylene terephthalate</td><td>1.11 - 1.59</td></tr>
<tr><td>Silicone</td><td>0.35 - 0.38</td></tr>
</table>
<u>Note:</u> Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.

<u>Note:</u> Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.
</td></tr>
<tr><td>Information on medicinal substances in the device</td><td>N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td>Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. This catheter has two separate tubes. The tubes go into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one tube of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second tube. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft.</td></tr>
<tr><td>Sterilization Information</td><td>Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.</td></tr>
<tr><td rowspan="2">Previous generations / variants</td><td>Name of previous generation</td><td>Differences from current device</td></tr>
<tr><td>N/A</td><td>N/A</td></tr>
<tr><td rowspan="10">Accessories intended for use in combination with the Tesio® Catheters</td><td>Name of Accessory</td><td>Description of Accessory</td></tr>
<tr><td>Guidewire</td><td>For general intravascular use to facilitate the selective placement of medical devices in the vessel anatomy.</td></tr>
<tr><td>Guidewire Advancer</td><td>Aid for introduction of guidewire into target vein.</td></tr>
<tr><td>Stylet</td><td>Assist in catheter insertion</td></tr>
<tr><td>Introducer Needle</td><td>Used for the percutaneous introduction of guidewires.</td></tr>
<tr><td>Catheter Securement Device</td><td>Stabilization device for compatible winged catheters</td></tr>
<tr><td>Catheter Plug</td><td>To block the catheter lumen and prevent blood loss after insertion and before the adaptor is attached</td></tr>
<tr><td>Tunneler</td><td>Instrument used to create a subcutaneous tunnel</td></tr>
<tr><td>Peelable Introducer</td><td>Introducers are intended to obtain central venous access to facilitate</td></tr>
</table>

		catheter insertion into the central venous system.
	Dilator	Designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein.
	End Cap	To keep clean and protect catheter luer between treatments.

4. Risks and warnings

Residual risks and undesirable effects

All surgical procedures carry risk. Medcomp has implemented risk management processes to proactively find and mitigate these risks as far as possible without adversely affecting the benefit-risk profile of the device. After mitigation, residual risks and the possibility of adverse events from use of this product remain. Medcomp has determined that all residual risks are acceptable.

Residual Harm Type	Possible Adverse Events Associated with Harm
Bleeding	Bleeding (May be severe) Femoral Artery Bleed Hematoma Retroperitoneal Bleed
Cardiac Event	Cardiac Arrhythmia Cardiac Tamponade
Embolism	Air Embolus
Infection	Bacteremia Endocarditis Exit Site Infection Septicemia Tunnel Infection
Perforation	Inferior Vena Cava Puncture Laceration of the Vessel Perforation of the Vessel Pneumothorax Right Atrial Puncture Subclavian Artery Puncture Superior Vena Cava Puncture
Thrombosis	Central Venous Thrombosis Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis

Miscellaneous Complications	Brachial Plexus Injury Cramping Death Femoral Nerve Damage Hemodynamic Instability Hemothorax Pleural Injury Swelling Thoracic Duct Laceration Venous Stenosis

Patient Residual Harm Category	Quantification of Residual Risks	
	PMS Complaints (01 January 2016 – 31 March 2025)	PMCF Events
	Units Sold: 109,046	Units Studied: 118
	% of Devices	% of Devices
Allergic Reaction	Not Reported	2.54%
Bleeding	0.015%	3.39%
Cardiac Event	0.004%	0.84%
Embolism	Not Reported	Not Reported
Infection	0.002%	3.39%
Perforation	Not Reported	Not Reported
Stenosis	Not Reported	Not Reported
Tissue Injury	Not Reported	Not Reported
Thrombosis	Not Reported	0.84%

Warnings and precautions

All warnings have been reviewed against the risk analysis, PMS, and usability testing to validate consistency between the sources of information. As per product IFU (IFU 40774-1BSI, IFU 40774-1JBSI, and IFU 40774-1NBSI), the Tesio® Catheters have the following warnings:

- Do not insert catheter in thrombosed vessels.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. If the guidewire becomes damaged, guidewire and any associated componentry must be removed together.
- Do not resterilize the catheter or accessories by any method.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE
- Do not re-use catheter or accessories as there may be a failure to adequately clean and decontaminate the device which may lead to contamination, catheter degradation, device fatigue, or endotoxin reaction.
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible or the use-by date has passed.

	• Do not use sharp instruments near the extension tubing or catheter lumen. • Do not use scissors to remove dressing. Precautions listed in the Tesio® Catheter IFUs are as follows: • Examine catheter lumen and extensions before and after each treatment for damage. • To prevent accidents, ensure the security of all caps and bloodline connections prior to and between treatments. • Use only Luer Lock (threaded) Connectors with this catheter. • In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter. • Before attempting catheter insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur. • Repeated overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. • The catheter will be damaged if clamps other than what is provided with this kit are used. • Avoid clamping near the Luer Lock and hub of the catheter. Clamping of the tubing repeatedly in the same location may weaken tubing. Additional warnings and cautions listed in the Tesio® Catheter IFUs are as follows: • Physician discretion is strongly advised when inserting this catheter in patients who are unable to take or hold a deep breath. • Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications. • Extended use of the subclavian vein may be associated with subclavian vein stenosis. • The length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure. • DO NOT grasp and pull the guidewire prior to releasing the J-Straightener. Damage to the guidewire may occur if it is pulled against the restraint of the J-Straightener. • When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire. • The Valved Peelable Introducer is not designed for use in the arterial system or as a hemostatic device.

	• DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold the introducer close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the introducer towards the vein, regrasp the introducer a few centimeters above the original grasp location and push down on the introducer. Repeat procedure until introducer is inserted to appropriate depth based on patient anatomy and physician's discretion. • Never leave sheath in place as an indwelling catheter. Damage to the vein will occur. • DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted. • Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time. Continue in this manner until the sheath is completely removed from the vessel, and then completely tear apart the sheath and discard. • Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire • Do not leave vessel dilator(s) in place as an indwelling catheter to avoid possible vessel wall perforation. • Do not advance guidewire with catheter into vein. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure. • DO NOT CLAMP THE LUMEN PORTION OF THE CATHETER. CLAMP ONLY THE CLEAR EXTENSIONS. DO NOT USE SERRATED FORCEPS, USE ONLY THE IN-LINE CLAMP(S) PROVIDED. • Failure to verify catheter placement may result in serious trauma or fatal complications. • Only clamp catheter with in-line clamps provided. • Excessive blood loss may lead to patient shock. • Extension clamps should only be open for aspiration, flushing, and dialysis treatment. • Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems. • Only a physician familiar with the appropriate techniques should attempt the following procedures. • Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients. • Do NOT pull distal end of catheter through incision as contamination of wound may occur.

Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2020 to 31 March 2025 there were 141 complaints for 44,856 units sold, giving an overall complaint rate of 0.31%. There were no death-related events. No events resulted in recalls during the review period.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

Summary of clinical data related to the subject device

The below table displays the device insertion case numbers identified and used for clinical performance evaluation in each clinical data source.

Clinical Literature	PMCF Data	Total Cases	User Survey Responses
3,020	118	3,138	3

Clinical performance was measured using parameters including but not limited to dwell time, catheter insertion outcomes, and adverse event rates. Critical clinical parameters extracted from these studies met standards set forth in the guidelines for the State of the Art. There were no unforeseen adverse events or other high occurrences of adverse events detected in any of the clinical activities.

Medcomp® catheters are subjected to, and must pass, simulated use testing intended to replicate use 3 times per week for 12 months as part of device development. The Tesio®/Duo-Jet® II/Chronic Twinline Catheter passed this testing. Although Medcomp® catheters contain no materials which degrade over time, fully functional catheters may be removed for other reasons, such as intractable infection, change of therapy (such as Renal replacement (transplant) or use of an arterio-venous graft/fistula). Published clinical literature does not always focus on the physical lifetime of a catheter for these reasons. In the case of the Tesio®/Duo-Jet® II/Chronic Twinline Catheter, 210 catheters had an 87.2 day [95%CI: 71.7 – 102.7 days] duration of use that has been found in clinical use reported to date. Based on this information, the Tesio®/Duo-Jet® II/Chronic Twinline Catheter has a 12-month lifetime; however, the decision to remove and/or replace the catheter should be based on clinical performance and need, and not any predetermined point in time.

Summary of clinical data related to the equivalent device (if applicable)

Clinical evidence from published literature and PMCF activities has been generated specific to known and unknown variants of the subject device. The equivalency rationale in the updated clinical evaluation report will demonstrate that the clinical evidence available for these variants is representative of the range of device variants in the device family.

There are no clinical or biological differences between variants within the subject device family, and the potential impact of the technical differences will be rationalized in the updated clinical evaluation report.

Summary of clinical data from pre-market investigations (if applicable)

No pre-market clinical devices were used for the device's clinical evaluation.

Summary of clinical data from other sources:

Source: Summary of Published Literature

Clinical evidence literature searches have found thirty two published literature articles representing 3,020 Tesio® device family specific cases. The articles include six randomized controlled trials (Atherikul et al., 1998, Richard et al., 2001, Schwab et al., 2002, Rosenblatt et al., 2006, Power et al., 2009, Power et al., 2014), eleven prospective studies (Millner et al., 1995, Mankus et al., 1998, Alloatti, et al., 2000, Biswal et al., 2000, Perini et al., 2000, Tovbin et al., 2001, Webb et al., 2002, Fry et al., 2008, Bertoli et al., 2010, Eloot etl a., 2023, and Tapolyai et al., 2025), thirteen retrospective studies (Prabhu et al., 1997, Di Iorio et al., 2001, Sheth et al., 2001, Bosch et al., 2004, Duncan et al., 2004, Pecorari et al., 2004, Wang et al., 2004, Alvarez et al., 2005, Ibrik et al., 2006, Royo et al., 2008, Jean et al., 2009, Premuzic et al., 2016, Power et al., 2010), and two case studies (Sosa et al., 2021 and Ratnayake et al., 2024).

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Source: LTHD Data Collection Survey Report

The Long-Term Hemodialysis Catheter Data Collection Survey was intended to gather safety and performance outcome information from sites that purchase Medcomp long-term hemodialysis catheters for use in EU MDR clinical evaluation. Responses were requested to be completed by physicians or other site employees with oversight and direction from a physician. The surveys were distributed globally to existing Medcomp customers. Responses were collected from twenty-one sites, spanning nine countries (Colombia, Croatia, El Salvador, Greece, Italy, Netherlands, Panama, Uruguay, and USA) across North America, South/Latin America, and Europe.

At least partial data was collected on 78 Tesio® catheter product family cases totalling at least 1,292 catheter days. Of these 78 cases, 77 were described as 10F and 52cm in length. One case was described as 12F and 20cm in length. Information was collected on Insertion Success (96.2%, n=78) and dwell time (215.3 days, 95% CI: 0 – 492.1, n=6). There was one report of catheter related blood stream infection (0.77 per 1,000 catheter days), one report of catheter associated venous thrombus (0.77 per 1,000 catheter days), and no reports of exit site infection or tunnel infection. All outcome measures were concluded to be within State of the Art safety and performance outcome measures from published literature except for dwell time and catheter associated venous thrombus rate. This is likely attributable to sample size, as both the sample mean of dwell time and sample rate of catheter associated venous thrombus were within State of the Art safety and performance outcome measures from published literature.

Source: PMCF_Medcomp_211

The Medcomp User Survey acquired responses from healthcare personnel familiar with any number of Medcomp's product offerings.

28 respondents responded that they or their facility have used Medcomp long-term hemodialysis catheters, with 3 of those respondents using the Tesio device. There were no differences in mean user sentiments within long-term hemodialysis catheters across State of the Art Performance and Safety Outcome Measures or between device types relating to safety or performance.

The following data points were collected from users of Medcomp long-term hemodialysis catheters (n=28):

- (Mean Likert Scale Response) Catheters function as intended – 4.8 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.8 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.7 / 5
- Dwell Time (n=26) – 167 days (95%CI: 130 – 203)

The following data points were collected from users of Medcomp Tesio® catheters (n=3):

- (Mean Likert Scale Response) Catheters function as intended – 4.3 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.3 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 3.6 / 5
- Dwell Time (n=3) – 80.8 days (95%CI: 0 – 299.6)

Source: PMCF_LTHD_242

The Long-Term Hemodialysis (LTHD) Truveta data analysis assessed safety and performance outcome information for Medcomp® and competitor devices present in Truveta Studio. Truveta data comes from a growing collective of more than 30 health systems that provide 17% of the daily clinical care across all 50 U.S. states from 800 hospitals and 20,000 clinics, representing the full diversity of the United States. The population used for data analysis was derived utilizing Truveta Studio's proprietary coding language (Prose) and unique device identifier (UDI) codes representing all saleable Medcomp® LTHD devices and LTHD devices distributed and/or manufactured by other companies.

41 Tesio® cases inclusive of several variant devices were collected. All cases were described as 10F and Straight Cases, configurations (straight), and lengths (36cm, 52cm), representation of 36cm and 52cm length catheters. The following State of the Art safety and performance outcome measures were observed for Medcomp Tesio® devices:

- Catheter Related Blood Stream Infection – 1.63 per 1,000 catheter days (95%CI: 0.6 – 3.54)
- Catheter Associated Venous Thrombus – 0 per 1,000 catheter days (95%CI: 0 – 1)
- Exit Site Infection – 0.27 per 1,000 catheter days (95%CI: 0.01 – 1.51)
- Tunnel Infection – 0 per 1,000 catheter days (95%CI: 0 – 1)
- Dwell Time – 63.44 days (95%CI: 32.53 – 94.35)

The catheter brand logistic regression model did not find that any Medcomp® catheter brands were statistically significantly associated with an increase of the incidence of CRBSI. The brand agnostic logistic regression found that pediatric age group (0–19 years), femoral vein insertion site, catheters that were the fourth or beyond in sequence for a given patient, split-tip designs, and pre-curved configurations were statistically significantly associated with the incidence of CRBSI. The Split Cath® III was associated with a statistically significant decrease in CRBSI incidence in the brand model (OR: 0.46 95%CI: 0.33 - 0.63), and both shorter catheter length (<=24cm) and smaller French size (<14.5F) in the brand agnostic model.

Overall summary of clinical safety and performance

Upon review of the data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating hemodialysis in patients in whom other therapies or conservative care are not indicated or desirable as determined by the physician, outweigh the overall and individual risks when the device is used as intended by the manufacturer. It is the manufacturer's and clinical expert evaluator's opinion that activities both complete and ongoing are sufficient to support the safety, efficacy, and acceptable benefit/risk profile of the Tesio®/Duo-Jet® II/Chronic Twinline catheters.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 40 days	↑	87.2 – 502.8 Days (**Summary of Published Literature**)	215.3 Days (**LTHD Data Collection Survey Report**) 80.8 Days **(PMCF_Medcomp_ 211)** Likert Scale Response 3.6 / 5 **(PMCF_Medcomp_ 211)**** 63.44 Days **(PMCF_LTHD_242)**
Procedural Outcomes	Greater than 93.3%	↑	87.8% - 100% insertions without complication (**Summary of Published Literature**)	96.2% insertions without complication (**LTHD Data Collection Survey Report**) Likert Scale Response 4.3 / 5 **(PMCF_Medcomp_ 211)****
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 4.8 incidents of CRBSI per 1,000 catheter days	↓	0.23 – 3.4 per 1,000 catheter days (**Summary of Published Literature**)	0.77 per 1,000 catheter days (**LTHD Data Collection Survey Report**) Likert Scale Response 4.3 / 5 **(PMCF_Medcomp_ 211)**** 1.63 per 1,000 catheter days **(PMCF_LTHD_242)**
Tunnel Infection Rate	Less than 2.8 incidents of tunnel infection per 1,000 catheter days	↓	0.22* – 0.48* (**Summary of Published Literature**)	No Events Reported (**LTHD Data Collection Survey Report**) Likert Scale Response 5 / 5 **(PMCF_Medcomp_ 211)**** 0 per 1,000 catheter days **(PMCF_LTHD_242)**
Exit Site Infection Rate	Less than 3.2 incidents of exit site infection per 1,000 catheter days	↓	0.28 – 2.01 per 1,000 catheter days (**Summary of Published Literature**)	No Events Reported (**LTHD Data Collection Survey Report**)

				Likert Scale Response 3.6 / 5 **(PMCF_Medcomp_211)** 0.27 per 1,000 catheter days **(PMCF_LTHD_242)**
Catheter Associated Venous Thrombus (CAVT)	Less than 3.04 incidents of CAVT per 1,000 catheter days	↓	0.35* - 1.36* (**Summary of Published Literature**)	0.77 per 1,000 catheter days (**LTHD Data Collection Survey Report**) Likert Scale Response 3.6 / 5 **(PMCF_Medcomp_211)** 0 per 1,000 catheter days **(PMCF_LTHD_242)**

*Event rate is an estimate based on available information in the article.
** PMCF_Medcomp_211 asked respondents, if they agreed on a scale of 1 -5, that their experience in relation to each outcome was the same or better than the benefit/risk acceptability criteria.

On-going or planned Post-Market Clinical Follow-up (PMCF)

Activity	Description	Reference	Timeline
Multi-center Patient-Level Case Series	Collect additional clinical data on the device by acquiring case data healthcare personnel familiar with the device.	PMCF_LTHD_241	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of similar devices by reviewing applicable standards, published literature, conference abstracts, guidance documents and recommendations; information relating to the medical condition managed by the device and medical alternatives available for the same target treated population.	SAP-HD	Q2 2026
Clinical Evidence Literature Search	Identify risks and trends with use of the device by reviewing any	LRP-HD	Q2 2026

	clinical data relevant to the device from published literature.		
Global Trial Database Search	Identify ongoing clinical trials involving Tesio® catheters.	N/A	Q2 2026

No emerging risks, complications or unexpected device failures have been detected from PMCF activities.

6. Possible therapeutic alternatives

The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent vascular access solution • Lower complication rate than hemodialysis via catheter	• Requires time to mature • Patients must sometimes self-cannulate	• Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	• Useful for quick vascular access without AV Fistula in place • Can be used as a bridge dialysis method between other therapies	• Not a permanent solution • Catheter dysfunction can disrupt regular treatment • Benefit is not equal for all patient populations	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Peritoneal Dialysis	• Less restrictive diet than hemodialysis • Does not require hospitalization, can be done in any clean place	• Clearance of impurities is limited by dialysate flow and peritoneal area	• Peritonitis • Septicemia • Fluid overload
Kidney Transplant	• Better quality of life compared to HD • Lower risk of death compared to HD • Fewer dietary restrictions compared to HD	• Requires a donor which can take time • More risky for certain groups (aged, diabetics, etc.) • Patient must take rejection medication for life	• Thrombosis • Hemorrhage • Ureteral blockage • Infection • Organ rejection • Death • Myocardial infarction • Stroke

Therapy	Benefits	Disadvantages	Key Risks
		• Rejection medication has side effects	
Comprehensive Conservative Care	• Less imposed symptom burden than dialysis • Preserves life satisfaction	• May aggravate clinical condition • Not designed to treat, but to minimize adverse events	• Treatment may not actually minimize risks associated with CKD

7. Suggested profile and training for users

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

As per guidelines stated from the International Society of Hemodialysis, if home dialysis is recommended, each patient will undergo a thorough training in order to obtain optimal results from home dialysis treatments. The objectives of the training program are to (1) provide the appropriate amount of information to ensure that the patient will be able to dialyze safely at home; (2) enable the patient to monitor and manage other elements of his or her chronic kidney disease, such as obtaining samples for lab work and maintaining appropriate nutrition and diet; and (3) help the patient and his or her care partner(s) cope with barriers and fears associated with home HD During training, the patient will also receive technical education on the operations and maintenance of the water treatment system.

During training, the ideal nurse trainer-to-patient ratio is typically 1:1. An idealized schedule of training is created, with weekly areas of focus and training objectives. In practice, however, training is individualized to address any identified learning barriers or risks for failure.

8. Reference to any harmonized standards and Common Specifications (CS) applied

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 14971	2019	Medical devices. Application of risk management to medical devices	Full
EN ISO 10555-1	2013+A1:2017	Intravascular catheters. Sterile and single-use catheters. General requirements	Full
EN ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Central venous catheters	Full
EN ISO 11607-1	2020+A1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2	2020+A1:2023	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
MEDDEV 2.7/1	Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	Full
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-18	2020+A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Full
EN ISO 10993-7	2008+ A1:2022	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants	Full
EN ISO 11135	2014 + A1: 2019	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	Full
BS EN 17141	2020	Cleanrooms and associated controlled environments. Biocontamination control	Full
ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	Full
ISO 14644-2	2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices	Full
EN ISO 11737-1	2018 + A1: 2021	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products	Full
BS ISO 11737-3	2023	Sterilization of health care products. Microbiological methods — Bacterial endotoxin testing	Full
ANSI/AAMI ST72	2019	Bacterial endotoxins-Test methods, routine monitoring, and alternatives to batch testing	Full
EN ISO 20417	2021	Medical Devices - Information supplied by the manufacturer	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 15223-1	2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Full
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	Full
ISO 594-2	1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock Fittings	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ASTM D4332-22	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Full
ASTM D4169-23e1	2023	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F2503-23e1	2023e1	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	Full
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers	Full
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	Full
MDCG 2020-7	2020	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies	Full
MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies	Full
MDCG 2022-9	2022	Summary of safety and clinical performance	Full
MDCG 2022-21	2022	Guidance on Periodic Safety Update Report (PSUR) According to Regulation EU 2017/745 (MDR)	Full
MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
EN ISO 11140-1	2014	Sterilization of health care products — Chemical indicators Part 1: General requirements	Full
EN ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories	Full
Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council	Full

PATIENTS

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Revision: SSCP-009 Rev. 6
Date: 05SEP2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

IMPORTANT INFORMATION

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

This SSCP is not intended to replace an Implant Card or the Instructions for Use to provide information on the safe use of the device.

1. Device identification and general information

Device trade name(s)	Tesio®, Duo-Jet® II , Chronic Twinline
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908278NQ
Date first CE certificate was issued for this device	January 1996

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays. Procedure trays come in different configurations.

Variant Devices:

Variant Description	Part Number
10F x 52cm Tesio (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)	10196-818-600-1 10196-821-100-1

Variant Description	Part Number
	10196-818-600S 10196-821-100S 10196-821-100-1
10F x 52cm Tesio (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)	10196-822-600-1 10196-825-100-1 10196-822-600S 10196-825-100S 10196-825-100-1
10F x 52cm Tesio (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)	10196-827-600-1 10196-830-100-1 10196-827-600S 10196-830-100S 10196-830-100-1
10F x 70cm Tesio (Arterial Cuff - 46cm From Tip) (Venous Cuff - 50cm From Tip)	1566S 1567S

Procedure Trays:

Catalog Code	Part Number(s)	Description
BFL-6E.	10196-827-600-1 10196-830-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFR-6E.	10196-822-600-1 10196-825-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFS-6E.	10196-818-600-1 10196-821-100-1	10F x 52cm Tesio® Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
BFL-6SE.	10196-827-600S 10196-830-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFR-6SE.	10196-822-600S 10196-825-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFS-6SE.	10196-818-600S 10196-821-100S	10F x 52cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
BFLS	10196-830-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 30cm From Tip)
BFRS	10196-825-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 25cm From Tip)
BFSS	10196-821-100-1	10F x 52cm Single Tesio® Catheter Set (Venous Cuff - 21.2cm From Tip)
BFR1070KDS	1566S 1567S	10F x 70cm Tesio® Catheter w/ Stylet Set (Arterial Cuff - 46cm From Tip) (Venous Cuff - 50cm From Tip)
NITSL21K	10196-818-600-1 10196-821-100-1	10F x 52cm Chronic Twinline Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
NITSL25K	10196-822-600-1 10196-825-100-1	10F x 52cm Chronic Twinline Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
DJLT2000L	10196-827-600-1 10196-830-100-1	10F x 52cm Duo-Jet® II Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)

DJLT2000R	10196-822-600-1 10196-825-100-1	10F x 52cm Duo-Jet® II Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)

Configurations of Procedure Trays:

Configuration Type
Dual Tesio® Catheter Set
Dual Tesio® Catheter Set w/ Stylet
Single Tesio® Catheter Set
Duo-Jet® II Catheter Set
Chronic Twinline Catheter Set

2. Intended use of the device

Intended purpose	Tesio® Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for single use only.
Indication(s)	Tesio® Catheters are indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis.
Intended patient group(s)	Tesio® Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.
Contraindications	• Known or suspected allergies to any of the components of the catheter or the kit. • This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.

3. Device description

Figure 1: Tesio® Catheters

Description of device	The Tesio®/Duo-Jet® II/Chronic Twinline Catheter is a long-term catheter. The catheter is single tubed. Two catheters are inserted into the target vein. The catheters remove and return blood through two separate lines. Priming volumes are printed on the lumen. A polyester cuff on the catheter tubing helps attach the catheter to the patient.
Materials / substances in contact with patient tissue	The percentage ranges below are based on catheter weights. The 52cm catheters weigh 18.02 grams. The 70cm catheters weigh 21.92 grams. **Material** / **% Weight (w/w)** Polyurethane / 49.52 - 52.01 Acetal copolymer / 22.35 - 24.37 Polyvinyl chloride / 8.75 - 9.55 Nylon / 4.35 - 4.74 Barium sulfate / 8.19 - 8.64 Stainless Steel / 1.97 - 2.14 Polyethylene terephthalate / 1.11 - 1.59 Silicone / 0.35 - 0.38 **Note:** The device should not be used if you are allergic to the above materials.

<table>
<tr><td></td><td colspan="2"><u>Note:</u> Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</td></tr>
<tr><td>Information on medicinal substances in the device</td><td colspan="2">N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td colspan="2">Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. This catheter has two separate tubes. The tubes go into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one tube of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second tube. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft.</td></tr>
<tr><td>Sterilization Information</td><td colspan="2">Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.</td></tr>
<tr><td rowspan="10">Description of accessories</td><td>Name of Accessory</td><td>Description of Accessory</td></tr>
<tr><td>Guidewire</td><td>Acts as a path for other components.</td></tr>
<tr><td>Guidewire Advancer</td><td>Helps guidewire introduction.</td></tr>
<tr><td>Stylet</td><td>Assist in catheter insertion.</td></tr>
<tr><td>Introducer Needle</td><td>Placed into the target vein to gain access.</td></tr>
<tr><td>Tunneler</td><td>Creates a pocket in between muscle and skin for catheter.</td></tr>
<tr><td>Catheter Securement Device</td><td>Stabilization device.</td></tr>
<tr><td>Catheter Plug</td><td>To block the catheter lumen after insertion and before the adaptor is attached.</td></tr>
<tr><td>Peelable Introducer</td><td>Used to get central venous access.</td></tr>
<tr><td>End Cap</td><td>To keep the catheter clean between treatments.</td></tr>
<tr><td>Dilator</td><td>Used to make the opening of a vessel larger.</td></tr>
</table>

4. Risks and warnings

Contact your healthcare professional if you believe you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document does not replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed	There have been 44,856 devices sold since January 2020. There are side effects and risks associated with the device. These include: • Infection

<table>
<tr><td></td><td>

- Bleeding
- Catheter Removal
- Catheter Replacement

These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is access for hemodialysis when alternatives are not suitable. These benefits outweigh the risks.
</td></tr>
<tr><td>Remaining risks and undesirable effects</td><td>

The Tesio® catheter is associated with risks. These include:

- Procedural Delays
- Thrombosis
- Infections
- Perforations
- Embolism
- Cardiac Event
- Dissatisfaction

These risks are consistent with risks of other dialysis catheters. They are not unique to the Medcomp product. Some of the most common reactions include infection. Infection may be associated with general surgical procedure and hospitalization. Infection may not always be device-related.

<table>
<tr><th rowspan="3">Patient Residual Harm Category</th><th colspan="2">Quantification of Residual Risks</th></tr>
<tr><th>Complaints (01 January 2016 – 31 March 2025)</th><th>Post Market Clinical Follow-Up Activity Events</th></tr>
<tr><th>Units Sold: 109,046</th><th>Units Studied: 118</th></tr>
<tr><th></th><th># of Cases Per Event</th><th># of Cases Per Event</th></tr>
<tr><td>Allergic Reaction</td><td>Not Reported.</td><td>1 Event in 3,933 Cases.</td></tr>
<tr><td>Bleeding</td><td>1 Event in 6,000 Cases.</td><td>1 Event in 2,950 Cases.</td></tr>
<tr><td>Cardiac Event</td><td>1 Event in 25,000 Cases.</td><td>1 Event in 118 Cases.</td></tr>
<tr><td>Embolism</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Infection</td><td>1 Event in 50,000 Cases.</td><td>1 Event in 2,950 Cases.</td></tr>
<tr><td>Perforation</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Stenosis</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Tissue Injury</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Thrombosis</td><td>Not Reported.</td><td>1 Event in 11,800 Cases.</td></tr>
</table>

</td></tr>
</table>

Warnings and precautions	The below are warnings, precautions, or measures to be taken by patient: • To reduce the risk of bacteria entering the catheter, wear a mask over your nose and mouth whenever the catheter is accessed. • Keep the catheter dressing clean and dry. The dressing should be changed by a medical professional at each dialysis session. • Avoid letting the catheter or catheter site go under water. Moisture near the catheter site can potentially lead to an infection. • Ask the doctor to explain the signs and symptoms of catheter infection. • Never remove the cap at the end of the catheter. The cap and clamps of the catheter must be kept closed when not being used for dialysis.
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 April 2024 to 31 March 2025.

5. Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device
The subject devices have been available since 1996. The CE Mark was received in 1996. US FDA clearance was in 1999. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review found 32 articles relating to the safety and/or performance of the subject device when used as intended. These articles include approximately 3,020 cases. Two patient level data survey received information on 118 catheters. 3 user surveys have been received related to this device. Findings from the clinical literature and data activities support the performance of the subject device. All data on the Tesio®/Duo-Jet® II/Chronic Twinline catheter has been evaluated. The benefits of the subject device outweigh the risks when the device is used as intended. The benefit of the device is allowing hemodialysis in patients in whom other therapies or conservative care are not desirable by the physician.
Safety
There is sufficient data to prove conformity to the applicable requirements. The device is safe and performs as intended and claimed by Medcomp. The device is state of the art for allowing long-term vascular access for hemodialysis in adult patients.

Medcomp has reviewed:

- Post-Market Data
- Medcomp Information Materials
- Risk Management Documentation

The risks are appropriately displayed and consistent with the state of the art. The risks associated with the device are acceptable when weighed against the benefits. There were 141 complaints for 44,856 units sold from 01 January 2020 to 31 March 2025. The complaint rate is 0.31%.

6. Possible therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation. The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent solution. • Lower complication rate than catheter.	• Requires time. • Patients must sometimes self-needle stick.	• Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	• Useful for quick access. • Can be used as a bridge between therapies.	• Not permanent. • Catheter dysfunction can happen. • Benefit may not be the same for everyone.	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Peritoneal Dialysis	• Less restrictive diet than hemodialysis. • Does not require hospitalization.	• Clearance of impurities is limited by flow and space.	• Peritonitis • Septicemia • Fluid overload
Kidney Transplant	• Better quality of life. • Lower risk of death. • Fewer dietary restrictions.	• Requires a donor. • More risky for certain groups. • Patient must take medication for life. • Medication has side effects.	• Thrombosis • Hemorrhage • Ureteral blockage • Infection • Organ rejection • Death • Myocardial infarction

Therapy	Benefits	Disadvantages	Key Risks
			• Stroke
Comprehensive Conservative Care	• Less imposed symptom burden. • Preserves life satisfaction.	• May aggravate clinical condition. • Not designed to treat.	• Treatment may not actually minimize risks associated with CKD.

7. Suggested training for users

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

Consult International Society of Hemodialysis guidelines. If home dialysis is recommended, you will undergo thorough training. The objectives of the training program are:

1) Give you information to dialyze safely at home.
2) Enable you to monitor and manage your disease.
3) Help you cope with fears and restrictions of home hemodialysis.

The ideal nurse trainer-to-patient ratio is typically 1:1. A training schedule will be created. Training will be individualized to your needs.

Abbreviation	Definition
AV	Arteriovenous
CE	Conformité Européenne (European Conformity)
CKD	Chronic Kidney Disease
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
dba	Doing Business As
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
KDOQI	Kidney Disease Outcomes Quality Initiative
PA	Pennsylvania
SSCP	Summary of Safety and Clinical Performance
USA	United States of America
w/w	Weight over Weight

Add copy to 'MDR Documentation' (Initial & Date): 09SEP2025